Claim 10 (and the claims that depend from it) was rejected indefinite with regard to the metes and bound of the claim in view of the use of the term "immunogen" and "pathogen[ic] agent." The Office Action asserted, "[B]ecause there are so many immunogen[s] and pathogen[s] in the art, the claim should point out which immnugen [sic, immunogen] and pathogen are intended in the said claim." The Office Action has not alleged that the claims are unclear. Thus, the rejection is based merely on the breadth of the claims. For the following reason, the applicants respectfully traverse.

The breadth of a claim alone is not a basis for rejecting the claim as indefinite. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). "If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph." MPEP § 2173.04. The applicants submit that the scope of the claims is clear (and the Office Action has not alleged that it is not). Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 10 (and the claims that depend from it) was rejected as indefinite in the recitation of "a systemic response," alleging that the specification failed to define what the definition of a human systemic response was. The applicants respectfully traverse.

The specification refers throughout to two types of immune responses (vis-à-vis the location of the response), local responses and systemic responses. The applicants submit that the ordinary artisan would readily understand that the term "systemic" is used in opposition to "local," *i.e.*, that a systemic immune response means a response that is not limited to a particular location and that is characterized, for example, by the presence of antibodies in the serum. (See specification page 1, lns. 28-30.) On the contrary, a local immune response of the mucosal type according to the invention is a mucosal immune response characterized by the presence of antibodies in the mucosal membranes or secretions. (See paragraph bridging pages 1 and 2 of the specification.)

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, Section 112 demands no more." *Miles Laboratories Inc. v. Shandon Inc.*, 27 USPQ2d 1123 (Fed. Cir. 1993). The applicants respectfully

submit that one of ordinary skill in the art would have no difficulty understanding the bounds of the claim with respect to the term "systemic."

Claims 10-15 were also rejected as indefinite for omitting essential elements, citing MPEP § 2172.01. The "omitted elements" were alleged to be the kind of immunogen used, the kind of human systemic response, the concentration of immunogen in the composition, *etc.*

First, the applicants respectfully submit that if certain elements are missing, it is incumbent on the Patent Office to specifically delineate either the missing elements or the gaps. By concluding the listing of missing elements with "*etc.*," the Patent Office leaves the applicants to speculate as to what other gaps the Patent Office may consider to be present in the claims and, consequently, the applicants are unable to craft an appropriate response.

Second, the section of the MPEP referred to by the Office Action states, "a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention." The Office Action has failed to explain how the claims fail to interrelate essential elements or why or how the three cited things are or connect essential elements.

With regard to the kind of immunogen, the applicants respectfully submit that the claims do not contain a gap by not reciting a particular kind of immunogen. There are no elements in the claims that require connection by recitation of a particular kind of immunogen. Recitation of "immunogen" is sufficient to connect administration and the elicitation of a response.

Similarly, there are no claim elements that require connection by a "kind" of systemic response. Recitation of "systemic response" clearly identifies the results of administering an immunogen.

With regard to the concentration of immunogen in the composition, the applicants respectfully submit that there is no gap in the claims that would be filled by recitation of a concentration. Furthermore, implicit in claim 10 is the fact that the immunogen must be administered in an amount effective to elicit the desired response. The applicants have amended claim 10 to make explicit that which was implicitly present.

In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of the § 112, second paragraph, rejections.

Rejection of claims 10-15 under 35 U.S.C. § 112, first paragraph

Claims 10-15 were rejected for lacking enablement for the full scope of the claims. The claims were rejected as non-enabled "for inducing [a] similar immune response [to that disclosed in the specification] in human[s] by injecting any or all immunogen[s] for any or all pathogen agent[s]." The Office Action cited the following in support:

a) Harman *et al.* (*Infect. Immun.* **62**, 412 (1994)) for teaching that intramuscular injection of O-antigen-protein did not protect naïve animals against subsequent challenge; and

b) Oien *et al.* (*Vaccine* **12**, 731 (1994)) for teaching that and RSV chimeric FG glycoprotein does not induce local IgA or IgG antibody production by parental administration.

The Office Action also asserted that the Applicants had not shown that injection of any or all immunogens of the pathogens recited in claim 14 could produce the recited immune response. For the following reasons, the applicants respectfully traverse.

The standard for examination of claims under the enablement requirement is well established:

In re Marzocchi, 169 USPQ 367 (C.C.P.A. 1971)

> As a matter of Patent Office practice, ... a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.
>
> [I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Furthermore, the evidence or reasoning supplied by the Examiner must be particularized and definite, not broad and general:

> [W]e do not consider that a broad allegation that the application disclosure is speculative, coupled with a recitation of various difficulties which might be encountered in attempting to

> put it into practice, and a further assertion that there might be still other difficulties which could not be foreseen, constitutes a sufficiently definite statement of a basis for rejection.

In re Chilowsky, 229 F.2d 457, 462 (C.C.P.A. 1956). The Applicants respectfully submit that the Office Action failed to provide particularized evidence or reasoning in support of the contention that the claims are not enabled.

With regard to the Office Action's assertions that the claims are not enabled for all immunogens of all pathogens or for all immunogens of all the pathogens recited in claim 14, the applicants note that the scope of the claims does not comprise all immunogens of (a) all pathogens (claim 10) or (b) all pathogens recited in claim 14. Rather, the scope of the claims is limited to "an immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes." The Office Action has not alleged that this scope has not been enabled.

With regard to the art cited in the Office Action in support of this enablement rejection, the applicants respectfully submit it is not indicative of the results one would achieve with the presently claimed method. Hartman *et al.* teach vaccination of **non-primate** guinea pigs via **mucosal** and **intraperitoneal** administration. Hartman *et al.* does not teach administration of an immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes into the thigh of a human or even a non-human primate. Furthermore, Hartman *et al.* deals with *Shigella*, which invades the human colonic epithelium. The colon ends at the rectum and, correspondingly, *Shigella* immunogens do not have a pathway into the rectal, genital and/or urinary mucous membranes. Because of these substantial differences, the Hartman *et al.* study is simply not indicative of the results of the presently claimed method.

Oien *et al.* teaches vaccination of **non-primate** mice via **intranasal** administration with respiratory syncytial virus (RSV). Oien *et al.* does not teach administration of an immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes into the thigh of a human or even a non-human primate. Furthermore, Oien *et al.* teaches **respiratory** syncytial virus, which does not have a pathway into the rectal, genital, or urinary mucous membranes. Because of these substantial differences, the Oien *et al.* study is simply not indicative of the results of the presently claimed method.

Because the rejection is not directed to the scope of the claimed method (*i.e.*, immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes) and the Harman *et al.* and Oien *et al.* references are not indicative the results achieved with the presently claimed method, the applicants respectfully submit that this non-enablement rejection is obviated. Even were there an allegation of non-enablement based on the proper interpretation of the claims, there is no scientific evidence or reasoning in support of the rejection remaining after disposal of Harman *et al.* and Oien *et al.*

In view for the foregoing, the applicants respectfully request reconsideration and withdrawal of this § 112, first paragraph, rejection.

Rejection of claims 10-15 under 35 U.S.C. § 102

Claims 10-14 were rejected as anticipated under § 102(e) by Morrow *et al.* (6,063,384), claims 10-15 were rejected as anticipated under § 102(e) by Whittle *et al.* (6,123,948) and Krieg *et al.* (6,339,068), claims 10-15 were rejected as anticipated under § 102(a) by Cohen *et al.* (5,654,174), and claims 10-15 were rejected as anticipated under § 102(b) by Carrano *et al.* (WO 95/26718). The basis for all rejections was that each patent publication disclosed intramuscular administration of an immunogen. The Office Action alleged that because the thigh (as recited in the present claims) is a muscle, each of the cited patent publications anticipated the present claims. For the following reasons, the applicants respectfully traverse.

The applicants respectfully submit that the Office Action has failed to establish a *prima facie* case of anticipation because it merely alleges that the genus of the prior art (*i.e.*, intramuscular administration) anticipates the presently claimed species (administration into the human thigh). To anticipate, the prior art must disclose each and every limitation of a claim. Furthermore, it is well settled that a genus does not inherently anticipate a species. *E.g., Corning Glass Works v. Sumitomo Electric U.S.A. Inc.*, 9 USPQ2d 1962 (Fed. Cir. 1989). There are 630 muscles in the human body, yet none of the cited art has been alleged to disclose the thigh as being the locus for vaccine administration. Furthermore, as noted on page 2, lns. 16-23, of the specification, Letchworth *et al.* taught that an intramuscular injection in an unspecified location of a glycoprotein induced a systemic response only. Accordingly, the locus of administration is important. Absent a teaching of the thigh as the site of

administration, the cited art simply cannot anticipate, as it does not disclose each and every limitation of the claims.

In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of the § 102 rejections.

Rejection of claims 10-15 under 35 U.S.C. § 103

Claims 10-15 were rejected as obvious over McBride *et al.* and Lehner *et al.* McBride *et al.* teaches immunization of guinea-pigs against HSV. McBride *et al.* injected vaccine subcutaneously between the scapulae and observed secondary responses both in the serum and at the vaginal mucosa of subsequently challenged guinea-pigs. Lehner *et al.* teaches subcutaneous immunization of non-human primates in the internal iliac lymph nodes to target the genitourinary -rectal associated lymphoid tissue and observed secretory IgA and IgG antibodies at the mucosal surfaces. The Office Action concluded that it would have been obvious to immunize a human subject by injection in the vicinity of the internal iliac lymph nodes, which the Office Action presumably envisions as including the thigh (although the Action failed to explicitly state so). The Office Action alleged there were no unexpected results of the claimed invention. For the following reasons, the applicants respectfully disagree.

Neither McBride *et al.* nor Lehner *et al.* teach or suggest administration to the human thigh to induce a local response in the rectal, genital, and/or urinary mucosal tissues, and the Office Action has not alleged that they do.

Nor do these references provide any teachings that would imbue the ordinary artisan with a reasonable expectation of success. McBride *et al.* is solely focused on inter-scapulae administration in guinea-pigs, which has essentially no predictive value with respect to the likelihood of success of administration to a human thigh. Lehner *et al.* teaches deep injection to the internal iliac lymph nodes of macaques but provides no teachings from which the ordinary artisan could derive a reasonable expectation that administration to *other than* the internal iliac lymph nodes and, in particular, to the thigh, would have the effect of inducing a local immune response in the rectal, genital, and/or urinary mucosal tissues. The Office Action has merely presumed that administration "near" the inter-

nal iliac lymph nodes is sufficient teaching to render obvious the presently claimed invention. But the Office Action has failed to identify any scientific support for such a presumption.

In view of the fact that cited art fails to teach or suggest administration to the thigh or to provide any teachings that would imbue the ordinary artisan with a reasonable expectation of success, the presently claimed invention cannot be obvious.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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APPLICATION SERIAL NO.: 09/720,513

Redlined Version of Amended Claim

10. (Amended) A method of inducing in a human a systemic immune response and a local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies, the method comprising parenterally administering to a human subject's thigh a composition comprising an immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes in an amount effective to elicit said immune responses.

APPLICATION SERIAL NO.: 09/720,513

Clean Version of Amended Claim

10. (Amended) A method of inducing in a human a systemic immune response and a local immune response of IgA, IgG or IgM antibodies or B cells secreting said antibodies, the method comprising parenterally administering to a human subject's thigh a composition comprising an immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes in an amount effective to elicit said immune responses.